

## REMARKS

### 1. Preliminary Matters

#### a. Status of the Claims

Claims 31-42 are pending in this application. Without prejudice to seeking claims of similar scope in a continuing application, claim 32 has been canceled without prejudice. Claim 33 is amended by removing the term “essentially.” Claims 34-42 have been withdrawn from consideration by the Examiner. Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the application. Upon entry of these amendments, claims 31 and 33 will be under active consideration.

#### b. New Declaration

On page 2 of the Office Action, the Examiner requests a newly executed Declaration because the previously submitted Declaration is allegedly defective for non-initialed or non-dated alterations. Without admitting to the defective nature of the Declaration, we are seeking to obtain a Supplement Declaration.

### 2. Patentability Remarks

#### a. 35 U.S.C. § 112, first paragraph – Written Description

On page 2 of the Office Action, the Examiner rejects claims 32 and 33 for allegedly failing to comply with the written description requirement. Specifically, the Examiner asserts that the specification does not provide written descriptive support for T cells that are reactive against only SEQ ID NOS: 1-6 in claim 32 or vaccines consisting essentially of T cells that are reactive against only SEQ ID NOS: 1-6 in claim 33. In view of the foregoing amendments, the written description issues are moot and the Applicant request that the rejections of claims 32 and 33 under 35 U.S.C. § 112, first paragraph, written description be withdrawn.

#### b. 35 U.S.C. § 112, first paragraph – Enablement

On page 3 of the Office Action, claims 31-33 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly lacks enablement for a vaccine comprising or consisting essentially of inactivated T cells that are reactive against, or only reactive against SEQ ID NOS: 1-6. The Examiner asserts that the specification has not enabled the breadth of the claimed invention because the claims encompass a composition that is a vaccine to be used prophylactically, including a vaccine composition comprising T cells that are only reactive against SEQ ID NOS: 1-6. The Examiner further alleges that the state of the art at the time of

filing is unpredictable in the absence of appropriate evidence of whether the claimed vaccine composition can be made and/or used, including prophylaxis. The Applicant respectfully disagrees.

Applicant respectfully submits that the Examiner has improperly misconstrued the scope of the claims. Specifically, the Examiner's focus is on the definition of "vaccine" when instead the focus should be on the recitation of "T cell vaccine." As was well known in the art, depletion of autoreactive T cells is not necessarily a prophylactic event, but rather a therapeutic event because the presence of the autoreactive T cells is required for the T cell vaccine to biologically act against or deplete in order to treat an autoimmune disease (for example multiple sclerosis).

T cell vaccines were well recognized in the art at the time of filing as therapeutic agents used to deplete the presence of autoreactive T cells. For example, Zhang et al., Science 261:1451-1454 (1993) teaches a T cell vaccine where T cells stimulated with full myelin proteins are used to deplete autoreactive T cell populations specific for MBP in humans suffering from multiple sclerosis. Moreover, the Examiner at page 3, fourth full paragraph, acknowledges the specification teaches a T cell vaccine that depletes autoreactive myelin-reactive autoimmune T cells in humans suffering from MS by stating the following:

The specification discloses that irradiated T cells specific for SEQ ID NO: 1-6, when administered to MS patients, results in a decline in EDSS (expanded disability status scores) and a decline in frequency of myelin-reactive T cells...

Accordingly by the Examiner's own characterization of the specification and what was known at the time of filing, the specification teaches T cell vaccines that contain inactivate T cells designed to recognize SEQ ID NOS: 1-6 and target autoreactive T cell populations that also recognize SEQ ID NOS: 1-6.

As discussed above, claim 32 is canceled without prejudice and issues related to the language "vaccine consists essentially of T cells" in claim 33 is moot. Accordingly, Applicant submits that the specification provides sufficient guidance as to how to make and use the claimed T cell vaccine invention of claims 31 and 33. In view of the foregoing amendment and remarks, the Applicant submits that the rejection of claims 31 and 33 under 35 U.S.C. §112, first paragraph, has been overcome and should be withdrawn.

**c. 35 U.S.C. § 112, second paragraph**

At page 4 of the Office Action, the Examiner rejects claim 33 as being indefinite. The Examiner alleges that claim 33 is indefinite in the recitation of “consists essentially of T cells that are reactive against SEQ ID NO:1-6.” The term “essentially” is deleted from claim 33, thereby rendering the Examiner’s rejection moot.

**3. Conclusion**

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

POLSINELLI SHALTON FLANIGAN SUELTHAUS PC

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On behalf of: Teddy C. Scott, Jr., Ph.D.  
Registration No. 53,573

By: /Paul A. Jenny/  
Paul A. Jenny  
Registration No. 59,014  
Customer No. 37808

POLSINELLI SHALTON FLANIGAN SUELTHAUS PC  
180 N. Stetson Ave., Suite 4525  
Chicago, IL 60601  
312.819.1900 (main)  
312.602.3955 (E-fax)  
312.873.3613 (direct)